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COMMENT

PATENTABILITY OF HUMAN GENETIC INFORMATION: EXPLORING ETHICAL DILEMMAS WITHIN THE PATENT OFFICE AND BIOTECHNOLOGY'S CLASH WITH THE PUBLIC GOOD

ERIC D. ZARD¹

INTRODUCTION

Increased advancements in biotechnology provide evidence for the remarkable capability of the human mind and have continually expanded what the Supreme Court has referred to as the "unforeseeable nature" of inventions.² The discovery of the structure of DNA in 1953 drastically transformed the study of biology.³ As scientists continue to make considerable advancements in understanding the fundamentals of DNA and that differences between human people stem from differences in DNA,⁴ new ethical concerns in both U.S. and international patent law have also been revealed. The Human Genome Project, which "was established to coordinate research aimed to identify all the genes in human DNA and to determine the order of the three billion chemical base pairs that make up human DNA," has not only resulted in the vast dissemination of knowledge to researchers and the general public, but has allowed for the identification of particular sets of genes and their relationship to human health and disease.⁵ Genetic sequencing technology, stemming from the Human Genome Project, has resulted in an increase in the number of patent applications by those attempting to secure exclusive rights over the newly discovered genetic information.

1. JD Candidate, 2009, University of St. Thomas School of Law; BS in Biology from the University of Minnesota. Special thanks and acknowledgement to University of St. Thomas Professor Teresa S. Collett, who provided guidance and wisdom in the production of this article. Additional acknowledgement to Dr. Janet E. Embretson, a registered patent attorney at Schwegman, Lundberg and Woessner, who provided knowledgeable technical and substantive edits and practical considerations in the production of this article.

2. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (landmark case determining that bioengineered microorganisms can be patented).

3. NUFFIELD COUNCIL ON BIOETHICS, *THE ETHICS OF PATENTING DNA 3* (2002), available at <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf> [hereinafter NUFFIELD COUNCIL ON BIOETHICS].

4. *Id.*

5. *Id.*

Researchers and scientists worldwide quickly recognized that the discoveries and knowledge revealed through the Human Genome Project potentially carried vast commercial value if intellectual property rights could be secured for this knowledge. About three thousand to five thousand patents on human genes and more than forty-seven thousand on inventions involving genetic material have been granted by the United States Patent and Trademark Office (USPTO).⁶ Advocates for allowing patent protection on genetic information assert that it provides an incentive to innovate, a means to recoup research and development (R&D) costs, and a guarantee for protection within the market, and it facilitates the disclosure of scientific knowledge.⁷ More recently, however, patents on genetic information, particularly human gene patents, have undergone increased scrutiny because of the potential effects on health care costs, the flawed rationale for allowing patents on genes, the ethical and moral concerns, and the questioning of whether genetic information meets patentability requirements.⁸

This paper provides an overview of human genetic information and the U.S. patent system. Part I provides a scientific analysis of the biological structure of the patentable subject matter at issue and a brief introduction to the Human Genome Project. Part II outlines the structure and purpose of the United States patent system to provide an understanding of what a patentee must currently undergo to be granted patent rights. Part III examines the various legal aspects regarding the patentability of genetic material, specifically human genetic information. This section explores the constitutionality of human gene patents and whether they meet utility and novelty requirements adopted by the USPTO. In addition, this section analyzes the ethical and public policy implications of gene patents on research in healthcare and diagnostic testing by making comparisons to the Food and Drug Administration's (FDA) requirements and exploring case studies often referred to by opponents of human gene patents. Moreover, it considers whether human genetic information has an inherent "special nature" and, if so, whether it should be taken into consideration by the USPTO. Finally, Part IV surveys two proposals for patent reform that would give patent examiners relief from the ethical dilemmas outlined in Part III. In total, this article aspires to increase congressional awareness and survey the debate as to whether United States patent regulation regarding human genetic information is in need of reform.

6. Robert Cook-Deegan, *Gene Patents*, in BIOETHICS BRIEFING BOOK 69 (Mary Crowley ed., 2008), available at http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/gene%20patents%20chapter.pdf.

7. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 6.

8. Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 Hous. J. HEALTH L. & POL'Y 65, 66 (2002) [hereinafter Andrews, *The Gene Patent Dilemma*].

PART I

DNA, Genes, Proteins and the Human Genome Project

Deoxyribonucleic acid (DNA) is essentially a collection of subunits, composed of a sugar-phosphate molecule with a nitrogen-containing side group (or base) attached to it, that string together to form two long polymers.⁹ This subunit serves as the building block of DNA and is called a nucleotide.¹⁰ The bases are of four types—adenine (A), guanine (G), cytosine (C), and thymine (T)—corresponding to four distinct nucleotides.¹¹ Each sugar is linked to the next via the phosphate group, creating a polymer chain composed of a repetitive sugar-phosphate backbone with a series of bases protruding from it.¹² The bases protruding from the strand bind to a complementary strand according to a strict rule defined by the structures of the bases: A binds to T and C binds to G.¹³ The result of the specific bonding rules is that each base pair forms one rung of the DNA “ladder.”¹⁴ Because the bases protrude from the sugar-phosphate chains at specific angles, the complementary pairing results in the two strands twisting around each other to form a double helix.¹⁵

The genetic instructions in DNA necessary to maintain a living organism act as the blueprint for life.¹⁶ Human life, and in fact all life, centers on the cells’ “ability to store, retrieve and translate” this genetic information.¹⁷ DNA also stores hereditary information that is passed on during cell division to its daughter cells and from one generation to the next via that organism’s reproductive cells.¹⁸ Living cells store the genetic instructions as its genes.¹⁹ Genes are “the information-containing elements that determine the characteristics of a species as a whole and of the individuals within it.”²⁰ Specifically, “genes are discrete segments of DNA molecules that contain the information necessary for producing products which are most often proteins.”²¹ While DNA molecules are relatively large and contain genetic instructions for thousands of proteins, the molecule is composed of smaller segments that code for specific proteins.²² Before the protein is produced,

9. BRUCE ALBERTS, ALEXANDER JOHNSON, JULIAN LEWIS, MARTIN RAFF, KEITH ROBERTS & PETER WALTER, *MOLECULAR BIOLOGY OF THE CELL*, 5 figs.1–2 (4th ed. 2002).

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.* at 6.

14. Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, 20 HEALTH L. 1, 3 (2008) (citing LORI B. ANDREWS ET AL., *GENETICS: ETHICS, LAW, AND POLICY* 17 (2002)).

15. *Id.*

16. ALBERTS ET AL., *supra* note 9, at 191.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 4.

22. ALBERTS ET AL., *supra* note 9, at 9.

however, the segments must be transcribed into separate mRNA²³ molecules.²⁴ There are typically three regions of a gene that are relevant to genetic patents and the production of proteins: (1) “exons” that code for proteins, (2) regions that mark the beginning and end of the gene, and (3) “introns” that do not code for proteins.²⁵ Before a protein can be constructed, the introns are removed from the gene by means of RNA splicing so that the sequence can be properly decoded.²⁶

The process of converting the coded sections of genes into proteins is called gene expression and is performed in two stages.²⁷ Gene transcription is the first stage and involves a process whereby “the gene’s DNA sequence is copied into RNA”²⁸ and then processed into mRNA.²⁹ Translation of the genetic sequence occurs in the second stage and involves a “process by which mRNA directs the synthesis of a protein.”³⁰ Proteins produced during gene expression “are composed of amino acids and are the molecules that carry out the work of the cell.”³¹ Similar to DNA and RNA, protein molecules are “formed by the stringing together of monomeric building blocks drawn from a standard repertoire that is the same for all living cells.”³² In total, all of the genetic information embodied by the complete DNA sequence dictates not only the nature of the cell’s proteins, but also when and where they are to be made.³³ An organism’s complete DNA sequences comprise its genome.³⁴

Until the 1970s, DNA was the most difficult cellular molecule for the biochemist to analyze.³⁵ Due to advancements in both recombinant DNA technology and techniques in DNA sequencing, it is now possible to isolate and characterize a specific region of almost any genome, to produce a virtu-

23. mRNA (messenger RNA) guide the synthesis of proteins according to the genetic instructions stored in the DNA. RNA, unlike DNA, is single-stranded and has a flexible backbone allowing it to form weak bonds with another part of the same molecule. This enables it to recognize other molecules by binding them selectively—and even to catalyze chemical changes in the molecules that are bound. *Id.* at 7.

24. *Id.* at 9.

25. Westhoff, *supra* note 14, at 3 (citing ANDREWS ET AL., *supra* note 14, at 22 and Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?* 7 COMP. L. REV. & TECH. J. 255, 256 (2003)).

26. *Id.*

27. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 4 box 1.1.

28. RNA is closely related to DNA, but the backbone is formed of a slightly different sugar (ribose instead of deoxyribose) and one of the four bases differs slightly (uracil in place of thymine). ALBERTS ET AL., *supra* note 9, at 6.

29. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 4 box 1.1.

30. *Id.*

31. *Id.*

32. ALBERTS ET AL., *supra* note 9, at 7.

33. *Id.* at 10.

34. U.S. Dep’t of Energy Human Genome Project, *About the Human Genome Project*, available at http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last visited Mar. 16, 2009) [hereinafter HGP Information].

35. ALBERTS ET AL., *supra* note 9, at 491.

ally unlimited number of copies of it, and to determine the sequence of its nucleotides in a few hours.³⁶ In 1990, the Human Genome Project³⁷ was established with the following goals: (1) identify all of the approximately 20,000–25,000 genes in human DNA; (2) determine the sequences of the three billion chemical base pairs that make up human DNA; (3) store this information in a database; (4) improve tools for data analysis; (5) transfer related technologies to the private sector; and (5) address the ethical, legal, and social issues (ELSI) that may arise from the project.³⁸ Since genes play a role in many human diseases and disorders, identification was thought to be the first step in the development of new diagnostic tests and treatments.³⁹

With the techniques used during the Human Genome Project, “an isolated gene can be altered (engineered) at will and transferred back into the germline of an animal or plant, so as to become a functional and heritable part of the organism’s genome.”⁴⁰ Technical breakthroughs “have provided new tools for determining the functions of proteins and of individual domains within proteins, revealing a host of unexpected relationships between them.”⁴¹ Notably, the new ways to efficiently mass produce protein hormones and vaccines made available large amounts of multiple different proteins, which ultimately resulted in the increased study of these complex molecules.⁴² At this point, however, further study of genetic information and the development of new treatments will depend on access, which could be limited depending on the future developments in the area of gene patenting.⁴³

PART II

An Overview of U.S. Patent Law

The Constitution of the United States in Article I, § 8, cl. 8 states that “Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries.”⁴⁴ The USPTO, an agency of the United States Department of Commerce, carries

36. *Id.*

37. The U.S. Department of Energy and the National Institutes of Health coordinated the Human Genome Project (HGP) and completed it in 2003. HGP Information, *supra* note 34.

38. *Id.* At the height of the HGP, large facilities with automated machines generated DNA sequences at the rate of 1,000 nucleotides per second, around the clock. ALBERTS ET AL., *supra* note 9, at 491.

39. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 3.

40. ALBERTS ET AL., *supra* note 9, at 491.

41. *Id.*

42. *Id.*

43. James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?* 37 WILLAMETTE L. REV. 637 (2001) (explaining the concern that gene patents will block access to genetic information, which in turn will inhibit the development of genetic technology and thereby adversely affect public health).

44. U.S. CONST. art. I, § 8, cl. 8.

out this power. This language has been interpreted by the United States Supreme Court to include:

(1) preserving public domain information through exclusion of subject matter that is deemed unworthy of patent protection, (2) providing incentive for private parties to invest in research, (3) enlarging the public storehouse of knowledge by providing incentive for inventors to publicly disclose their inventions, and (4) encouraging the commercial use of inventions.⁴⁵

Patents in the United States are commonly viewed as “a contract between the people, as represented by the federal government, and an inventor.”⁴⁶ That is, the inventor receives a time-limited exclusive right for the invention,⁴⁷ and in exchange, “[t]he inventor provides information to the public which can be used by anyone to create improvements and new inventions.”⁴⁸ Granting a temporary “monopoly” provides inventors with an incentive to create and disclose new inventions.⁴⁹ A patent provides its owner the ability to prevent others from practicing the invention and thus keeps the competition at bay.⁵⁰ Inventors have an interest in being rewarded for their effort, typically by being able to recoup financial investments in research and development and profit from their inventions.⁵¹ Having this exclusive right and security can be extremely valuable. For example, in the pharmaceutical industry, a new drug can cost several hundred million dollars to develop and introduce to the market.⁵² The assurances of patent protection allow the inventor the opportunity to enjoy the “fruits of that investment” and relieve concern that others may profit from his or her invention.⁵³ Congress has determined that these temporary monopolies are the most efficient means of “promoting the progress of science and the useful arts.”⁵⁴

45. Bradshaw, *supra* note 43 (citing JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES § 1.04 [4] (1999) (analyzing a series of U.S. Supreme Court patent cases and distilling from them these enumerated principles)).

46. Carol A. Schneider et al., *Patenting Life: A View from the Constitution and Beyond*, 24 WHITTIER L. REV. 385, 387 (2002).

47. A “patent” is a property right which grants to the inventor the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States for a period of twenty years from the date on which the application for the patent is filed. U.S. Patent & Trademark Office, General Information Concerning Patents, <http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent> (last visited Mar. 15, 2009).

48. Schneider et al., *supra* note 46, at 387.

49. *Id.* at 388.

50. *Id.* (citing 1 PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS § 1.03, 1–6 (2d ed. 1986)).

51. *Id.*

52. *Id.*

53. *Id.*

54. Schneider et al., *supra* note 46, at 387.

For a patent application to become a patent, the application must meet the statutory requirements of the Patent Act of 1952, which states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title."⁵⁵ Patentability depends on the inventors' ability to meet several conditions, including: utility, novelty, non-obviousness, written description, and enablement.⁵⁶ Particularly in examining a patent application involving genetics, an "inventor must (1) identify novel genetic sequences, (2) specify the sequence's product, (3) specify how the product functions in nature (i.e., its use), and (4) enable one skilled in the field to use the sequence for its stated purpose."⁵⁷

The USPTO is made up of several different examining groups⁵⁸ with jurisdiction over certain assigned fields of technology.⁵⁹ The role of a patent examiner is to: (1) review patent applications to assess if they comply with basic format and legal rules; (2) carry out a search of patents, patent applications, and nonpatent documents, and the substantive examination of the applications; (3) issue an action letter rejecting various claims and objecting to various informalities (the applicant is given a short time in which to respond and, if desirable, amend the claim); and (4) review relevant prior art that is disclosed by the inventor or their patent attorney.⁶⁰ While the USPTO does not have jurisdiction⁶¹ to enforce patent rights or over issues of patent infringement, an appeal process for patent application does exist.⁶²

55. 35 U.S.C.A. § 101 (2009).

56. Westhoff, *supra* note 14, at 4.

57. U.S. Dep't of Energy Human Genome Project, *Genetics and Patenting*, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml (last visited Mar. 23, 2009).

58. In 2007, the USPTO was comprised of 8,913 federal employees, including 5,477 patent examiners. The same year, 474,955 patent applications were received and 182,901 patent applications were granted. This massive influx of patent applications results in a latency period of nearly 32 months. U.S. PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2007 (2007), available at <http://www.uspto.gov/web/offices/com/annual/2007/2007annualreport.pdf>; U.S. PATENT STATISTICS CHART CALENDAR YEARS 1963–2008, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited Mar. 23, 2009).

59. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 78.

60. *Id.*

61. The U.S. Federal Courts have jurisdiction over issues involving patent claims such as enforcement and infringement. U.S. Patent and Trademark Office, *General Information Concerning Patents*, <http://www.uspto.gov/web/offices/pac/doc/general/index.html> (last visited Mar. 23, 2009).

62. The Board of Patent Appeals and Inferences is responsible for handling appeals for patents that have been rejected. *Id.*

PART III

Patentability of Human Genetic Information: Legal and Ethical Concerns

American jurisprudence is riddled with legal and ethical debates, and patent law is no different. One ongoing debate, and the topic of this article, gained momentum in 1980 when the U.S. Supreme Court held in *Diamond v. Chakrabarty* that a live, human-made microorganism was patentable subject matter.⁶³ Addressing the standard necessary to satisfy patentable subject matter requirements, the Court broadly determined it to include “anything under the sun that is made by man.”⁶⁴ The Court did carve out exceptions to this rule, however, the two most notable being that mere ideas and things that occur in nature are not patentable.⁶⁵

Patentability of human genetic information falls under the more expansive debate over “gene patenting.”⁶⁶ In the current state of U.S. patent law, living matter (including subcellular matter such as DNA) is considered patentable, so long as it is altered from its natural form.⁶⁷ The term “gene patent” does not have any legal basis, but is typically one that seeks protection for “the sequence of a molecule of DNA that codes for a protein.”⁶⁸ The USPTO definition of “gene patent,” however, includes a broader scope and has resulted in patents for polynucleotides⁶⁹ that correspond to “a full-length protein encoding gene, a gene fragment, a regulatory region, a cDNA molecule, or a genomic region of unknown function.”⁷⁰ Under this definition, gene patents may also be granted for methods of diagnosing disease by using particular genes or methods of using proteins for diagnostic testing.⁷¹ This broad definition raises legal and ethical concerns about the validity of

63. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Chakrabarty filed a patent application towards a genetically engineered bacterium which was capable of breaking down crude oil. The bacteria were not naturally occurring and were thought to have a significant use for treating oil spills.

64. *Id.* at 309.

65. *Id.* The Court noted that there are exceptions to this general rule: laws of nature, physical phenomena and abstract ideas are not patentable.

66. Throughout this article, the term “human genetic information” and “gene patenting” may be used interchangeably. However, it is important to note that the debate over “gene patenting” typically includes patentability of animal and plant genetic information as well. Here, “human genetic information” is used to refer to all aspects concerning the genetic information of humans, including: DNA, RNA, proteins, cDNA, mRNA, etc.

67. Schneider et al., *supra* note 46, at 391.

68. *Id.*

69. Polynucleotides are a polymetric chain of nucleotides, essentially DNA or RNA sequences. MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 901 (10th ed. 2001).

70. Gregory C. Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents*, 15 RICH. J.L. & TECH. 1, 7 (2008); see Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 312 (2007) (providing examples of issued patents that claim a variety of different forms of genetic compositions); see also Ellis, Parts II.B-C (discussing the patentability of genetic compositions).

71. Bradshaw, *supra* note 43.

these patents and the potential effects on both public benefit and social welfare. The legal debate largely focuses on whether human gene patents are patentable subject matter and whether the intent of the framers to “promote the progress of science” is satisfied.⁷² Coupled with the legal debate, some commentators argue that ethical and moral issues must be considered in developing strong public policy and weighed when determining whether U.S. patent law should grant human gene patents.⁷³ A discussion of the balance between the potential deleterious consequences to healthcare, the restraints on commercial and academic research, and the special nature of DNA must be included in this debate.

A. *Legal Foundation of Patents on Human Genetic Information*

The USPTO has been granting patent protection to gene sequences for a number of years.⁷⁴ More recently, however, the legitimacy of these patents has been questioned on the grounds of constitutionality and subject matter requirements. The most controversial areas of this legal debate revolve around whether patents on human genetic information are unconstitutional and whether they meet the novelty and utility requirements of the Patent Act of 1952.⁷⁵

1. *Are Patents on Human Genetic Information Unconstitutional?*

The Supreme Court explained that the purpose for granting patents is to provide incentives for inventiveness and research efforts.⁷⁶ It was the Framers’ understanding that if inventors were granted temporary exclusive rights to their invention, they would be properly incentivized by the possibility to not only recover research and development costs but also to have a prospect at receiving a profit from their labor.⁷⁷ Proponents argue that “patents facilitate genetic research by encouraging investment in what would otherwise be a risky financial investment.”⁷⁸ Further, due to the intellectual and financial investments and the ever expanding timeline associated with potentially returning a profit, biotechnology industry insiders insist that patents continue to be made available for genetic material.⁷⁹ According to in-

72. See generally Schneider et al., *supra* note 46.

73. See generally NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3; Westhoff, *supra* note 14.

74. Westhoff, *supra* note 14, at 13.

75. Ellis, *supra* note 70, at 6.

76. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974) (further explaining that “[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.”).

77. Westhoff, *supra* note 14, at 6 (citing Schneider et al., *supra* note 46, at 387–88).

78. Bradshaw, *supra* note 43, at 653.

79. *Id.*; see Oversight Hearing on Gene Patents and Other Genomic Inventions Before the House Subcomm. on Courts and Intellectual Property, Comm. of the Judiciary, 106th Cong. 74 (2000) (statement of Dennis J. Henner, PhD, Senior Vice President, Research, Genentech, Inc.).

siders, this is especially true for “small biotechnology companies because most of these companies have no revenue from sales to fund research,”⁸⁰ but instead “they depend on venture capital and public market investors.”⁸¹ Therefore, advocates argue that if patents on genetic information are barred, companies without other sources of revenue to fund research will lose their ability to attract investors, ultimately resulting in significant delay in the research process, or worse, the research never being performed.⁸² Advocates reason that by allowing human gene patents, Congress satisfies its role of promoting “the progress of science” since it effectively removes the fear that invaluable genetic research will cease.⁸³

Conversely, those challenging the constitutionality of these patents argue that Congress is *not* promoting the progress of science because gene patents prohibit genetic research, introduce barriers to developing treatments and cures for genetic disease, and can potentially delay public availability of scientific information.⁸⁴ In addition, opponents challenge the validity of the position that without innovation, genetic research will cease.⁸⁵ Commentators have stated that “researchers desiring to study a complete gene may have to obtain expensive licenses from several patent holders who have rights to different fragments of that gene.”⁸⁶ Moreover, commentators propose that “if a researcher wanted to study a genetic disease in hopes of developing a treatment or cure, he or she could potentially have to obtain licenses from every scientist who has patented the disease gene or a mutation of that gene.”⁸⁷ As an example, critics frequently rely on two patented genes in particular, BRCA1 and BRCA⁸⁸—two identified

80. Tufts Center for the Study of Drug Development estimated that the fully capitalized cost to develop a new drug, including studies constructed after receiving regulatory approval, averages \$897 million. Tufts Center for the Study of Drug Development, *Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million*, May 13, 2003, <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29> (last visited Mar. 15, 2009).

81. *Id.*

82. *Id.*

83. Westhoff, *supra* note 14, at 7 (citing Bradshaw, *supra* note 43, at 653).

84. *Id.* at 6–7.

85. *Id.* at 7.

86. *Id.* (citing Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCI.* 698, 699 (1998)). The Heller article discusses what has been colloquially referred to as the “Tragedy of the Anticommons Theory.” It is essentially a play on the Garrett Hardin article “The Tragedy of the Commons,” suggesting that people underuse scarce resources because too many owners block each other due to recent proliferation of intellectual property rights in biomedical and biotechnology research. Garrett Hardin, *The Tragedy of the Commons*, 162 *SCI.* 1243 (1968).

87. *Id.*

88. Myriad Genetics secured patents on BRCA1 and BRCA2, the mutations, and screening tests. Mutations in BRCA1 and BRCA2 account for an estimated 5–10% of breast cancer cases and a significantly elevated risk for ovarian cancer. Cook-Deegan, *supra* note 6.

genes which affect the risk of breast and ovarian cancer in women⁸⁹—stating that:

[i]n order to compile viable, useful data, an investigator studying this disease would not only have to obtain licenses from each of the two inventors holding patent rights to these genes, but would also have to negotiate with the hundreds of other scientists who have discovered and patented mutations of these genes.⁹⁰

The real concern expressed by these commentators is that “anyone who owns a patent to a gene or a mutation can refuse another scientist a license or charge exorbitant prices for the license and stymie research efforts.”⁹¹ Based on this position, critics conclude that gene patents result in an improper deviation from Congress’s role “to promote the progress of science” and, therefore, that gene patents are unconstitutional.⁹²

Critics have also challenged proponents who claim that invaluable genetic research will cease if incentives are removed by highlighting the differences between pharmaceutical research and genetic research, relying on language in *Chakrabarty*.⁹³ Commentators have argued that the isolation and purification of genetic material does not require the same motivation as pharmaceutical drug development—pointing out that “[m]olecular biologists were attempting to identify genes long before the [USPTO] made clear that genes could be patented.”⁹⁴ Further, some argue that unlike the FDA clinical service approval process for pharmaceutical drugs, which is a highly regulated process that typically presents another financial burden on the inventor, the need to financially compensate an inventor researching an application for a particular isolated gene is not as great because the FDA does not have the same requirements for genetic clinical testing.⁹⁵ These commentators rely on Chief Justice Burger’s analysis in *Diamond v. Chakrabarty*, where he notably stated that “legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the un-

89. Lori B. Andrews, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL’Y L. & ETHICS 403, 403 (2004) [hereinafter Andrews, *Gene Patents*].

90. Westhoff, *supra* note 14, at 7 (citing Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 84–85).

91. *Id.* (citing Heller & Eisenberg, *supra* note 86, at 699). It is important to note that a common law defense to infringement exists and has become known as the “Experimental Use Doctrine.” While courts have narrowly construed this exception, it serves as a valid defense if the patent was used (1) for a legitimate business reason, and (2) solely for amusement, or (3) to satisfy idle curiosity, or (4) for strictly philosophical inquiry. *See generally* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

92. Westhoff, *supra* note 14, at 5.

93. *See id.* at 7; *see also* Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 77–79.

94. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 77.

95. *Id.* (citing LORI ANDREWS, *FUTURE PERFECT: CONFRONTING DECISIONS ABOUT GENETICS* 126 (2001) (noting that the FDA must review labeling materials on genetic testing kits as part of the premarket approval and because most genetic tests are marketed as services, not kits, they are not subject to FDA premarket approval)).

known any more than Canute could command the tides.”⁹⁶ Since “there are fewer social, economic, and public health costs [associated with] granting a drug patent than a gene patent”⁹⁷ and because language in U.S. patent law precedent supports the notion that research will continue without incentive, critics reason that removing patent protection will not result in cessation of invaluable genetic research. As a result, critics have urged courts to recognize that the federal government’s attempt to “promote the progress of science” by granting patents for human genetic information is fruitless, and therefore, these patents should be deemed unconstitutional.

Proponents of human gene patents have largely relied on well-established Supreme Court precedent to validate their argument that gene patents are constitutional. These commentators have rebutted the criticism that gene patents interfere with research by challenging the study used to formulate its conclusion.⁹⁸ The particular survey in question reported that twenty-one percent of geneticists’ reasons for withholding post publication information, data, or materials were based on the “need to protect the commercial value of the results.”⁹⁹ Proponents argue that the survey was “silent as to whether the researchers who were actually prevented from obtaining information or materials because of commercial interests were themselves basic researchers with no commercial ambitions.”¹⁰⁰ Accordingly, they assert that the “true test [is] whether . . . biomedical researchers without commercial interests are prevented from acquiring materials, not whether researchers with commercial interest are withholding materials.”¹⁰¹ Relying on a more recent survey,¹⁰² the evaluators conclude that the results “offer little empirical basis for claims that restricted access to [intellectual property] is currently impeding biomedical research.”¹⁰³ With this evidence, proponents conclude that there is insufficient evidence to confirm that gene patents specifically interfere with strictly academic research,¹⁰⁴ and therefore no conclusive evidence exists to suggest that gene patents impede on Congress’s attempts to “promote the progress of science.”¹⁰⁵

96. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

97. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 77.

98. Ellis, *supra* note 70, at 26. See generally Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473 (2002) (national survey to determine the nature, extent, and consequences of data withholding in academic genetics).

99. Campbell et al., *supra* note 98, at 478.

100. Ellis, *supra* note 70, at 14 (asserting that this omission is critical to concluding that such data signifies a hindrance on noncommercial biomedical research).

101. *Id.* at 27.

102. *Id.* (citing John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCI. 2002, 2002 (2005)).

103. *Id.* (quoting Walsh et al., *supra* note 102, at 2002). Please note the “Experimental Use Doctrine” outlined at note 91.

104. Ellis, *supra* note 70, at 27 (citing Walsh et al., *supra* note 102, at 2003).

105. *Id.*

Regardless of the debate over survey credibility and which evidence should be given the most weight in determining whether gene patents detract from or contribute to the Congressional power of “promot[ing] the progress of science,” it is of central importance that the USPTO has continued to issue patents for genetic information and that U.S. patent law precedent has yet to declare these patents unconstitutional.

2. *Do Patents on Human Genetic Information Meet Utility Requirements?*

Section 101 of the Patent Act requires that, for an invention to be patentable, it must be “useful.”¹⁰⁶ In the majority of patent applications, establishing the utility standard is relatively easy compared to the other requirements.¹⁰⁷ When it comes to gene patents however, defining the standard to meet this requirement can be more difficult.¹⁰⁸ The difficulty in establishing this standard arises because “the useful properties of a gene (such as its ability to bind to another complementary strand of DNA for diagnosis or its ability to code for a particular protein) are not ones that the scientists [have] invented, but rather are natural, inherent properties of genes themselves.”¹⁰⁹

Biotechnological breakthroughs surrounding “the advent of automated high-through put sequencing techniques” and the Human Genome Project in 1990 resulted in scientists “generat[ing] large quantities of raw genomic data.”¹¹⁰ While the information contained in this newly revealed genetic information was largely unknown, competition between the private and public sectors developed as organizations began to seek patent protection for what they deemed commercially valuable information.¹¹¹ In turn, controversy surrounding the “utility” standard emerged when Dr. J. Craig Venter¹¹² applied for 6,800 expressed sequence tags¹¹³ and subsequently “sent

106. Westhoff, *supra* note 14, at 4. See generally 35 U.S.C. § 101 (2008).

107. Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?*, 7 COMP. L. REV. & TECH. J. 255, 259 (2003), available at <http://smu.edu/stlr/articles/2003/Spring/Chavez.pdf>.

108. *Id.* (stating that “[in] cases where biotechnological material at issue cures disease or is used as a pharmaceutical product, it is easy to satisfy the utility standard” compared to applicants for biotechnological patents).

109. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 71 (arguing that when a gene is discovered and knowledge about the sequence of the gene is used to identify whether a particular patient has a mutation in that gene, there are no expensive clinical trials necessary).

110. Bradshaw, *supra* note 43, at 642 (citing Martin Enserink, *Patent Office May Raise the Bar in Gene Claims*, 287 SCI. 1196, 1196–97 (2000)).

111. Bradshaw, *supra* note 43, at 642 (stating that “[b]ecause genetic research is a cumulative endeavor, the work of downstream researchers depends on access to upstream discoveries. The owners of upstream discoveries can put a price on such access, transforming raw scientific data into a valuable commodity.”).

112. J. Craig Venter was the founder of commercially-based Celera Genomics that competed with the federally funded Human Genome Project to complete the sequencing of the human genome. Ellis, *supra* note 70, at 17 n.51 (citing Jonathan Kahn, *What’s the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL’Y REV. 417, 420 (2003)).

20,000 genes sequences to the [USPTO], [applying for] patents to the sequences and to procedures that would be used to diagnose disorders [associated] with [the] genes.”¹¹⁴ Faced with negative response from the scientific community and protest by the general public, the USPTO enacted new utility guidelines known as the 2001 Utility Examination Guidelines (Guidelines).¹¹⁵ Importantly, the Guidelines created the “specific, substantial, and credible” test for utility, which has been applied as a stricter standard for establishing usefulness of a gene patent.¹¹⁶ To determine whether a particular patent meets these factors, patent examiners may consult a training manual issued by the USPTO.¹¹⁷ First, the manual states that “a utility is ‘specific’ when it is particular to the subject matter claimed.”¹¹⁸ Second, the “substantial utility” requirement is determined by an examination of the patent’s “real world” use.¹¹⁹ This means that “if no further experimentation is required to show an immediate benefit of the genetic sequence for which a patent is desired,” then this typically was satisfactory.¹²⁰ Finally, “a utility is ‘credible’ if a person skilled in the art would accept that the invention is immediately available for the [disclosed] use.”¹²¹

Prior to the adoption of the Guidelines, attempts to bar the patentability of genetic information altogether or attempts to statutorily limit the breadth of a particular gene patent by arguing that the patent failed to meet the utility standard were the most convincing.¹²² However, because more information is required in order to receive a patent for genetic information, this criticism has become moot.¹²³ Nevertheless, gene patent critics remain concerned that “the revised [G]uidelines will not stop abuse” of what they

113. Ellis, *supra* note 70, at 17. Expressed sequence tags are small pieces of DNA sequence (usually two-hundred to five-hundred nucleotides long) that are generated by sequencing either one or both ends of an expressed gene. National Center for Biotechnology Information, *Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources*, <http://www.ncbi.nlm.nih.gov/About/primer/est.html> (last visited Apr. 9, 2009).

114. See iBrief, *The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH. REV. 8, ¶ 5 (2001) (Venter’s applications were denied by the USPTO. The USPTO went on to require that an inventor show a level of utility beyond the gene’s use as a research tool.) [hereinafter iBrief, *The Fate of Gene Patents*].

115. Westhoff, *supra* note 14, at 4 (citing iBrief, *The Fate of Gene Patents*, *supra* note 114).

116. iBrief, *The Fate of Gene Patents*, *supra* note 114, ¶¶ 11–14.

117. *Id.*

118. Westhoff, *supra* note 14, at 5 (quoting iBrief, *The Fate of Gene Patents*, *supra* note 114).

119. iBrief, *The Fate of Gene Patents*, *supra* note 114, ¶ 13. This portion of the test is “designed to prevent the granting of patents if further research must be performed before the genetic material can be used for a specific purpose or benefit.”

120. *Id.*

121. *Id.* Before the 2001 guidelines went into effect, researchers were often granted patents simply by claiming that the ESTs were useful as general genetic research tools. Under the new guidelines, however, an EST is not specifically useful unless the patent application also identifies the complete gene with which the EST is associated.

122. Bradshaw, *supra* note 43, at 649–50 (citing Stephen G. Kunin, Written Description Guidelines and Utility Guidelines, 82 J. PAT. & TRADEMARK OFF. SOC’Y 77, 93 (2000)).

123. *Id.*

believe to be “relatively lax utility requirements.”¹²⁴ These same critics point to multiple factors that portray the heightened utility requirement as “an obstacle, rather than a substantial bar, to patentability.”¹²⁵ Critics argue that regardless of whether patent agents are given training manuals and more objective standards, the utility requirements are “inherently difficult to define and will always remain the subject of uncertainty.”¹²⁶ The resulting uncertainty, according to critics, is counterproductive and may potentially establish an additional burden for less financially endowed inventors.¹²⁷ That is, because the burden is on the applicant to establish patentability and because patent examiners have limited financial resources, critics recognize that uncertainty increases the ability of applicants to cleverly navigate past a potential utility rejection.¹²⁸ Second, critics are concerned that the Guidelines will conflict with judicial precedent, resulting in the federal courts declaring the utility requirements invalid.¹²⁹ Third, some commentators suggest that the new standards may be counterproductive because they could cause scientists to focus their research toward developing products or isolating genes that are certain to meet the Guidelines.¹³⁰ Their concern is that the scientific community, as a whole, would be harmed because potentially beneficial research would be discouraged since the products of that research would be ineligible for patent protection and therefore be regarded as having insignificant value.¹³¹

In general, commentators who doubt the effectiveness of heightened utility standards in curtailing gene patents ground their discontent on the fear that biotech companies will take advantage of “opportunistic protection of subsequently discovered uses.”¹³² For example, Human Genome Sciences (HGS), a company based in Maryland, obtained a patent after filing a relatively generic application regarding the utility of a gene known as HDGMR10.¹³³ At the time that HGS filed the application, HGS was unaware that the protein encoded by the gene was a receptor essential for HIV

124. Bradshaw, *supra* note 43, at 651 (citing Enserink, *supra* note 110, at 1197) (claiming that “thousands of patent applications have been filed on genes . . . without a single experiment” and were filed solely on characterization through “computer searches”).

125. Bradshaw, *supra* note 43, at 652.

126. *Id.*

127. *Id.* (arguing that practitioners drafting patent applications for genetic information are obligated to exploit the uncertainty to the advantage of their client and that one skillful in drafting applications would have little trouble overcoming the standard for a client with seemingly unlimited resources).

128. *Id.*

129. *Id.*

130. *Id.*

131. Bradshaw, *supra* note 43, at 652.

132. Ellis, *supra* note 70, at 10.

133. *Id.*

infection.¹³⁴ Within the same year, scientists at the National Institutes of Health had identified and named the receptor.¹³⁵ Although HGS was oblivious to the significance of the protein encoded by HDGMR10, HGS maintains an “exclusive right to license the patent to another biotechnology that is using the CCR5 protein product in an effort to develop an HIV vaccine.”¹³⁶

While it is reasonable for critics to express discomfort over extreme circumstances such as those outlined above, advocates for gene patents contend that the Guidelines have “corroborated the USPTO’s intent to issue patents [for] genetic composition under requisite circumstances.”¹³⁷ Further, advocates tout that the Guidelines give patent examiners direction in determining “real world” utility and reduce the possibility for opportunistic patenting.¹³⁸ Finally, in response to the concern that the federal courts may declare the Guidelines invalid, proponents notably rely on *In re Fisher*, which indoctrinated the Guidelines into common law.¹³⁹

In regard to this aspect of the debate, both positions maintain valid reasoning as to whether genetic patents meet the proper utility standard. However, by adopting Guidelines to create a more definitive utility standard and providing training manuals for patent examiners to ensure objective review processes, the USPTO has indicated its intent to grant patents to a more limited group of inventions and, therefore, critics’ arguments have become less persuasive.¹⁴⁰ Absent significant evidence to conclude that the Guidelines create an unfair legal prejudice, it is unlikely that successful gene patents will be revoked on the theory that they fail to meet the subject matter requirement of utility.

3. *Do Patents on Human Genetic Information Meet the Novelty Requirement?*

As a bedrock principle, to obtain a patent, an inventor must create something new.¹⁴¹ According to section 102 of the Patent Act, an invention is novel unless it is known or used, has already been patented, or is described in a printed publication within the United States or a foreign coun-

134. *Id.*; see Bradshaw, *supra* note 43, at 651 (citing Enserink, *supra* note 110, at 1197) (noting that the human gene patented by HGS was found using publicly owned sequence information generated by the Human Genome Project).

135. Ellis, *supra* note 70, at 10. The name of the protein is CCR5.

136. *Id.*

137. *Id.* at 11.

138. *Id.*

139. *Id.* at 12 (citing *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (rejecting a patent application for ETSs corresponding to certain maize genes because the inventor was unaware of the precise structure or function of the genes encoded by the ETSs when the patent application was filed)).

140. Westhoff, *supra* note 14, at 8.

141. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 357 (2007).

try.¹⁴² The question of whether patent applications for genetic discoveries meet the novelty requirement under section 102 is often “further complicated by the fact that it overlaps in many respects with the question of whether genes are patentable subject matter.”¹⁴³ Similar to utility requirements, advocates and critics differ in their beliefs about whether gene patents satisfy the novelty requirement of section 102.

Critics of patenting human genetic information argue that this information cannot meet the novelty requirement because the product’s own qualities allow it to be produced naturally within the human body and therefore statutory bars should be established to remove the possibility of patent protection and ownership.¹⁴⁴ Similarly, critics argue that because of the Human Genome Project and other similar projects performed in laboratories to identify and isolate genetic information, the patent applications should be denied since they would be trying to establish an exclusive right to “prior art.”¹⁴⁵ Further, some critics contend that “genes should be statutorily excluded from patentability because they are mere discoveries, not inventions.”¹⁴⁶ Genes in their natural form are typically determined to be ineligible for patent protection unless certain processes are performed to meet the novelty requirements.¹⁴⁷ For example, if a scientist wishes to create a usable template for a particular genetic sequence so that it has a higher probability of satisfying the novelty requirement, he or she may choose to remove the introns and leave only the exons to be reassembled, thus creating a cDNA molecule that performs the same function as the original.¹⁴⁸ The concern is that this isolated and purified gene has “the same function as a naturally-occurring gene” and the patent holder’s application is actually an attempt to claim ownership of the original genetic sequence as it is found in the human body.¹⁴⁹ Instead, critics have proposed “that because the human genome is literally the blueprint of humankind’s common heritage, it is a perfect candidate for an international treaty that ‘would vest all right in the human genome in humanity as a whole and provide that all of humanity should benefit from its exploration’”¹⁵⁰

142. See 35 U.S.C. § 102 (2002).

143. Westhoff, *supra* note 14, at 5 (citing Chavez, *supra* note 107, at 259).

144. Bradshaw, *supra* note 43, at 646.

145. *Id.* at 647 (additionally stating that “[t]his argument contemplates denying patent protection to substances that were subject to prior cultural knowledge or use . . . such as genetically engineered pharmaceuticals that were derived from healing herbs used by pre-industrialized societies.”).

146. *Id.* at 647–48.

147. Westhoff, *supra* note 14, at 5.

148. *Id.* (citing Chavez, *supra* note 107, at 259) (notably stating that, “the USPTO holds that laboratory-created cDNA molecules meet the statutory requirements for novelty”). cDNA, or complementary DNA, is a molecule that contains only the uninterrupted coding sequences of a gene. ALBERTS ET AL., *supra* note 9, at 503–04.

149. Westhoff, *supra* note 14, at 8; see also Bradshaw, *supra* note 43, at 647–48.

150. Bradshaw, *supra* note 43, at 647; see also David Keays, *Patenting DNA and Amino Acid Sequences—An Australian Perspective*, 7 HEALTH L.J. 69, 72–76 (1999)). While some commenta-

Alternatively, those supporting human gene patents contend that the debate as to whether products of nature should be patented has been settled by nearly a century of legislative history and judicial precedent. Proponents challenge the critics' argument by relying on the broad language used by the Supreme Court in *Diamond v. Chakrabarty* where it stated that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"¹⁵¹ Moreover, advocates argue that based on the decision in *In re Bergstrom*,¹⁵² "isolated and purified compositions are not excluded from patentability."¹⁵³ Finally, proponents rely on the Guidelines, which they concede will not allow for gene patents simply for "sequence data that represent genes as they naturally occur with human chromosomes."¹⁵⁴ Thus, proponents argue that the proper assurances are in place to guarantee that a gene patent will only be granted if it is useful as a "pharmaceutical drug, screening assay, or other application."¹⁵⁵

In sum, the USPTO continues to grant patents for human genetic information without being challenged on legal grounds by the court or legislature. In the legal debate as to whether human genetic information should be statutorily excluded from patent protection, critics seeking change through the courts appear to have an uphill battle due to the strong U.S. patent law precedent and application Guidelines that have been directed against frivolous gene patent applications. However, the critics have not gone unnoticed. The USPTO has evidenced its willingness to make appropriate changes to the application process by promulgating the Guidelines.¹⁵⁶ Similarly, legislative activity (although recently rejected) proves that the public at large is becoming aware that patent reform may be necessary.¹⁵⁷

B. Ethical Issues and Public Policy Surrounding the Patentability of Human Genetic Information

As previously discussed, patent law precedent and legislative history provide that genetic information is patentable subject matter and that gene

tors have characterized this concept, known as the "Common Heritage Principle," as a policy rather than a legal argument, it is an international legal concept that conveys equal property interests to all people.

151. Bradshaw, *supra* note 43, at 647–48 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980)).

152. *In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (holding that hormones isolated and purified from human prostate glands were held to exist in a state not found in nature); *see also* *Parke Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912) (determining that extracted adrenaline was patentable).

153. Ellis, *supra* note 70, at 8.

154. *Id.* at 9 (citing Bradshaw, *supra* note 43, at 648–49).

155. Bradshaw, *supra* note 43, at 648–49.

156. Notice, 66 Fed. Reg. 1092 (Jan. 5, 2001).

157. The Genomic Research Accessibility Act was introduced to prohibit the patenting of human genetic material. This bill was rejected. *See generally* Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2(a) (1st Sess. 2007).

patents are capable of withstanding challenges on constitutional grounds.¹⁵⁸ Unlike the legal debate, where proponents of gene patents can more easily revert to supporting statutory and judicial language, the ethical debate involves a robust discussion between balancing innovation and incentive with the protection of the “public good”¹⁵⁹ and the “common heritage of humanity.”¹⁶⁰ While commentators have suggested that U.S. patent law is “morally neutral,”¹⁶¹ it is difficult for proponents to deny the existence of ethical and moral principles surrounding patents on genetic information. Critics of gene patents view these principles as the fundamental building blocks for establishing a strong public policy argument, which they believe in turn, may influence patent reform.

Although it would be naive to represent that ethical and moral considerations exist in isolation from other interests concerning gene patents, it is difficult to address the interplay between these issues on a broad scale. For that reason, this section attempts to logically separate the debate into the two main policy considerations, as represented by commentators advocating for and against genetic patents.

1. *Healthcare Concerns Surrounding Patents on Human Genetic Information*

The debate surrounding potential deleterious consequences to healthcare is fervently contested and multifaceted. Accordingly, this section will first discuss whether genetic patents discourage research that could potentially promote healthcare. Second, this section will examine the debate on the impact that human gene patents have on access to genetic diagnostic tests. Throughout this particular debate, critics and proponents make utilitarian objections and debate the proper means to incentivizing innovation while preserving both quality and access to healthcare.

Those opposing gene patents argue that because these patents inhibit research that can contribute to healthcare, it is unethical and against public policy to allow patents on human genetic information.¹⁶² As noted previously, the patent law grants exclusive rights for twenty years from filing.¹⁶³

158. Ellis, *supra* note 70, at 12.

159. “Public Good” is a phrase commonly referred to in economics. Generally, it refers to a “good” that if consumed by one individual, does not reduce availability of the good for consumption by others, and similarly, no one can be excluded from using the good. As an example, a fireworks display funded by an entrepreneur can be observed by people from their backyards or windows and the entrepreneur cannot charge a fee for consumption. *See generally* Tyler Cowen, *Public Goods*, THE CONCISE ENCYCLOPEDIA OF ECONOMICS (2d ed.), <http://www.econlib.org/library/Enc/PublicGoods.html> (last visited Dec. 12, 2008).

160. *Common Heritage of Mankind*, ENCYCLOPÆDIA BRITANNICA ONLINE, <http://www.britannica.com/EBchecked/topic/930727/common-heritage-of-mankind> (last visited Dec. 3, 2008).

161. Bradshaw, *supra* note 43, at 649 (citing SCHLICHER, *supra* note 45, § 1.04).

162. Westhoff, *supra* note 14, at 8 (citing Heller & Eisenberg, *supra* note 86).

163. *See supra* text accompanying note 47.

During that twenty year period, patent holders are not required to actually use or develop the invention,¹⁶⁴ which means that they can prevent others from profiting from their invention even though they are not profiting from the invention themselves.¹⁶⁵ More commonly, however, patent holders take advantage of their patent and either exclusively use the patented invention or license the patented invention to others.¹⁶⁶ Commentators fear that gene patents will limit clinical testing, restrict innovation, and inhibit the discovery of potentially higher-quality and lower-cost methods.¹⁶⁷

Likewise, there is concern that a “patent holder might forbid anyone from using the genetic sequence it has patented, even if the patent holder does not itself offer a diagnostic test using that sequence.”¹⁶⁸ In genetic research, this issue arises when inventors working in different laboratories receive exclusive rights to “various fragments of a single gene” and either refuse to license their patent or make it difficult for a researcher to study a particular genetic disorder because they cannot track down who owns the patent rights.¹⁶⁹ High transactional costs and the fear of infringing another’s patent rights may deter scientists all together, thus “depriving humanity of potential treatments and cures for diseases.”¹⁷⁰ With the increasing research surrounding pharmacogenomics and in the current state of economy, it becomes more probable that transactional costs will rise or that patent holders wanting to achieve financial security will more actively enforce their exclusive patent rights, ultimately impeding the progression of healthcare and breaching public policy.¹⁷¹

Additionally, critics have cited multiple surveys which they believe evidence the effect that gene patents have had in inhibiting research toward promoting healthcare.¹⁷² The findings of these surveys concluded that: (1) “[a]cademic researchers with funds from companies are four times as likely as those without such funds to report that trade secrets have resulted from their research;”¹⁷³ (2) “[o]ne of every five medical scientists has delayed publication of research results for at least half a year in order to protect financial interests;”¹⁷⁴ (3) “scientists who were directly engaged in the com-

164. Andrews, *Gene Patents*, *supra* note 89, at 409. This is different than under European patent law, where if the patent holder fails to use the invention, he or she loses the exclusive right.

165. *Id.*

166. *Id.* at 407 (citing Yee Wah Chin, *Unilateral Technology Suppression: Appropriate Antitrust and Patent Law Remedies*, 66 ANTITRUST L.J. 441, 450 (1998)).

167. Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 579 (2002).

168. Andrews, *Gene Patents*, *supra* note 89, at 408–09.

169. Westhoff, *supra* note 14, at 8 (citing Heller & Eisenberg, *supra* note 86, at 699).

170. *Id.*

171. *Id.*

172. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 80.

173. *Id.* (summarizing results from David Blumenthal et al., *University-Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCI. 1361, 1362 (1986)).

174. *Id.* (summarizing results from David Blumenthal et al., *Withholding Research Results in Academic Life Sciences*, 277 JAMA 1224, 1224 (1997)).

mercialization of their research were three times more likely to delay publication and twice as likely to refuse to share information than those who were doing basic work;"¹⁷⁵ (4) "[a]mong the life scientists, geneticists were the most likely to withhold data;"¹⁷⁶ (5) "[47%] of geneticists surveyed had been denied requests from other faculty members for information, data, or materials regarding published research;"¹⁷⁷ (6) "more than [20%] of geneticists surveyed said that they intentionally withheld data to protect the commercial value of their results;"¹⁷⁸ and (7) "[28%] of geneticists surveyed reported that they were unable to duplicate published research because other academic scientists refused to share information, data, or materials."¹⁷⁹ These studies confirm the argument that patents on genetic information delay researchers in both academia and commercial institutions, and thus, significantly obstruct research in healthcare. Critics argue that delay resulting from an "uncooperative academic community" may deter scientists from performing the research altogether.¹⁸⁰ For example, commentators often highlight a case where the study of a particular gene associated with autism was obstructed when researchers withheld a patient's tissue sample so as to be the first to discover the gene and reap the financial benefits.¹⁸¹

Delay in the patent application process,¹⁸² however, can also have significant consequences. These delays have given some applicants an opportunity to exploit other researchers by using what is commonly referred to as a "submarine patent" strategy.¹⁸³ In the context of genetic research, the problem typically arises while a patent is making its way through the application process and a second, independent researcher, discovers the same genetic sequence and begins to develop a diagnostic screening test based on that sequence.¹⁸⁴ Unbeknownst to the second researcher, "when the original patent application is granted" the first researcher can exclude "the second

175. *Id.* (summarizing results from Blumenthal et al., *supra* note 173, at 1226–27).

176. *Id.* (summarizing results from Blumenthal et al., *supra* note 173, at 1227–28).

177. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 80 (summarizing results from David Blumenthal et al., *Data Withholding in Academic Genetics*, 473 JAMA 473, 477 (2002)).

178. *Id.* (summarizing results from David Blumenthal et al., *supra* note 177, at 478).

179. *Id.* at 81 (noting that this particular statistic is particularly troubling since the scientific community typically holds peer review in the highest regard).

180. Westhoff, *supra* note 14, at 8 (citing Heller & Eisenberg, *supra* note 86, at 699).

181. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 80 (citing Eliot Marshall, *Whose DNA Is It Anyway?*, 278 Sci. 564, 564 (1997)).

182. Patent applications often take more than 32 months. See U.S. Patent and Trademark Office, *supra* note 61.

183. This "tactic" results when a broad "submarine patent" is filed and continuous amendments are made to the file to hold the patent in the patent office until "an individual later tries to use the idea contained in the patent," at which point, "the inventor will demand royalties or threaten to file a lawsuit." Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 86 (citing Steven Blount, *The Use of Delaying Tactics to Obtain Submarine Patents and Amend Around a Patent that a Competitor Has Designed Around*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 11, 13 (1999)).

184. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 86.

researcher from making its test or treatment available.”¹⁸⁵ If the second researcher still desires to make use of his or her research, the owner may demand an exorbitant licensing fee.¹⁸⁶ As previously cited, this problem was realized in 2000 when HGS received a patent for the HDGNR10 receptor.¹⁸⁷ Only after being later discovered by researchers at the National Institutes of Health, did HGS comprehend that the patent was for the CCR5 receptor, a critical receptor in AIDS research.¹⁸⁸ Thereafter, HGS was able to exclude National Institutes of Health from all “research on CCR5 function and use in development of an HIV treatment.”¹⁸⁹ Accordingly, critics have argued that such egregious outcomes create disincentives for further research and will eventually distract researchers from making discoveries that would benefit public health.¹⁹⁰

In contrast, proponents for gene patents contend that such patents actually encourage innovation within healthcare.¹⁹¹ Similar to the rebuttal on the constitutionality of gene patents, proponents largely challenge critics’ utilitarian objections rather than the moral objections.¹⁹² Specifically, proponents dispute the survey results used to formulate the critics’ argument.¹⁹³ By querying whether these surveys have addressed the proper policy question, drawing on more recent statistical evidence, and reviewing the legislative history of human gene patents, proponents claim that human gene patents favor research that promotes healthcare.¹⁹⁴

Proponents first argue that the statistics relied on by critics are largely based on anecdotal evidence gathered from a single third-party survey which sought to determine the full range of genetic data withheld by academic geneticists.¹⁹⁵ Although the rising interest in patent metrics has resulted in new empirical work, legal scholars and economists alike have long recognized the difficulty in interpreting data on patents.¹⁹⁶ Further, proponents argue that the survey fails to address “whether the researchers who were actually prevented from obtaining information or materials because of commercial interests were themselves basic researchers with no commercial

185. *Id.* (citing Blount, *supra* note 183, at 13).

186. *Id.*

187. *Id.* at 87 (citing Pat Carson & Melissa Mandrgoc, *Gene-Based Drugs Challenge Patent Process*, 226 N.Y.L.J. 73, 73 (2001)); *see also* Arthur Allen, *Who Owns My Disease?*, MOTHER JONES, Nov. 1, 2001, at 52).

188. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 86.

189. *Id.* at 88.

190. *Id.*

191. Ellis, *supra* note 70, at 13.

192. *Id.*

193. *Id.* at 13–14.

194. *Id.*; *see also* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677 (2007); Holman, *supra* note 70.

195. Ellis, *supra* note 70, at 13–14 (arguing that the survey relied on was not unique to gene patents, but rather it concerned all “life scientists”).

196. Adleman & DeAngelis, *supra* note 194, at 1707.

ambitions.”¹⁹⁷ Proponents contend that this omission is critical to the debate and assert that a conclusion as to whether gene patents hinder biomedical research cannot be made without it.¹⁹⁸ Instead, they proposed a slightly different test that they believed would more accurately address the critics’ policy concerns.¹⁹⁹ The test inquires “whether biomedical researchers without commercial interests are prevented from acquiring materials.”²⁰⁰ Proponents suggest that if a researcher is pursuing a non-commercial interest and is not dissuaded from acquiring material or performing research that promotes healthcare, then there has been no breach of public policy.²⁰¹ Since the critics’ proposed evidence is unsupportive, proponents continue their argument by relying on more recent surveys of biomedical researchers in universities, government, and nonprofit institutions.²⁰² These surveys questioned whether patents could be blamed for blocking access to biomedical research materials and reported that “while access to research materials at times may be strict, ‘the patent status of requested materials had no significant effect’ on why those materials were restricted.”²⁰³ The study looked at “[a] huge number of patents . . . used in research laboratories throughout the U.S. every day, including human gene patents” and reported that these patents have had a “relatively minor impact on basic research.”²⁰⁴ Relying on the support from this survey, proponents turned to the legislative history regarding human gene patents.²⁰⁵ Since patents are not self enforcing²⁰⁶ and the survey found that “basic research activities are rarely, if ever, the subject of patent infringement lawsuits,” proponents suggest that researchers are largely choosing to either ignore the existence of a patent or “at least not letting the existence of a patent dictate their research agenda.”²⁰⁷ In addition, as mentioned above, proponents contend that precedent within U.S. patent law recognizes an “experimental use exception.”²⁰⁸ Therefore, proponents conclude that because no evidence exists to suggest that researchers are behaving irrationally or being deterred from conducting research to pro-

197. Ellis, *supra* note 70, at 14 (citing Campbell et al., *supra* note 98, at 473).

198. *Id.*

199. *Id.*

200. *Id.*

201. Ellis, *supra* note 70, at 15 (citing Walsh et al., *supra* note 102, at 2003).

202. *Id.* (citing Walsh et al., *supra* note 102, at 2002).

203. *Id.* (citing Walsh et al., *supra* note 102, at 2003). The survey also reported that of those surveyed, none declared that third-party patents stopped their research and only 1% stated that research was delayed as a result of another party’s patent.

204. Holman, *supra* note 70, at 305 (citing Walsh et al., *supra* note 102, at 2002–03).

205. Holman, *supra* note 70, at 306.

206. This means that “the mere issuance of a patent does not legally restrict the ability of anybody to do anything unless and until the patent owner successfully sues for patent infringement.” Holman, *supra* note 70, at 305.

207. *Id.*

208. Ellis, *supra* note 70, at 15–16; *see also* *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).

mote healthcare, patents on human genetic material do not violate public policy.²⁰⁹

Critics are also concerned that if patents continue to be issued for genetic information, it would obstruct advancement in the area of diagnostic testing.²¹⁰ Specifically, critics worry that patent holders will only allow for their laboratory to test for the patented gene,²¹¹ and that companies engaged in this sort of conduct will make the performance of diagnostic testing difficult because only they can test for “their” gene.²¹² Critics have relied on one survey which reported that due to a recently issued patent for a test to screen for hereditary haemochromatosis²¹³ (HFE test), “twenty five percent of the laboratories had been deterred from offering a test due to the enforcement of a patent or [lack of a] license.”²¹⁴ Behind this survey was Smith Kline Beecham Clinical Laboratories, who after purchasing an exclusive license for the patented HFE test, wrote letters to laboratories instructing them to stop performing or developing tests for the patented gene.²¹⁵ In the alternative, they requested “an upfront fee of \$25,000 from academic laboratories, and [five] to [ten] times more than this from commercial laboratories, plus royalties of as much as \$20 fee per test.”²¹⁶

As another example, critics of human gene patents often cite to *Greenberg v. Miami Children’s Hospital Research Institution, Inc.*, a case dealing with a patent for diagnosing Canavan disease.²¹⁷ Canavan disease “leads to a degeneration of the brain, causing the children to lose their vision, experience seizures, and eventually require tube feeding.”²¹⁸ Children suffering from this disease rarely make it into their teenage years.²¹⁹ Over time, with the cooperation between families with children suffering from Canavan disease and a team of researchers, the particular gene causing the disease was isolated, allowing for genetic labs across the country to provide prenatal

209. Holman, *supra* note 70, at 305 and n.60.

210. Andrews, *Gene Patents*, *supra* note 89, at 407.

211. *Id.*

212. *Id.*

213. Merz et al., *supra* note 167, at 578. This survey was performed in November 1998 through September 1999 and consisted of laboratory directors and supervisors. The purpose was to determine the impact of the HFE patent and the SBCL licensing strategy. “Hereditary Haemochromatosis is a common autosomal recessive disease, affecting 1 in 200 to 1 in 300 people of northern European descent . . . [a]s much as 80–85% of haemochromatosis is caused by the two most common mutant alleles of the HFE gene (C282Y and H63D).” *Id.* at 577.

214. Andrews, *Gene Patents*, *supra* note 89, at 408.

215. Merz et al., *supra* note 167, at 578.

216. *Id.*; Andrews, *Gene Patents*, *supra* note 89, at 408.

217. *Greenberg v. Miami Children’s Hospital Research Institution, Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003); *see also* Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 91 (explaining that “Canavan disease is a rare genetic disease that occurs most frequently in Ashkenazi Jewish families.”).

218. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 91.

219. *Id.*

and carrier screening.²²⁰ In an attempt to circumvent this tragic disease, Rabbi Josef Ekstein established a genetic testing program in New York to screen and test for Canavan disease.²²¹ The program made significant progress until the gene was patented and the patent owner sent cease and desist letters and demanded royalties for tests performed.²²² The ultimate result was that fewer tests could be performed and, as emphasized by Ekstein, “there’s no question that [more] Canavan children [would] be born.”²²³

After comparing patents associated with pharmaceuticals and patents on human genetic information, it is further contended that a patent on genetic information wrongly grants monopolistic protection and, even if the protection is the only means available, it inappropriately compensates gene patent holders.²²⁴ Commentators argue that the significant difference between patents on pharmaceuticals and gene patents is that, unlike pharmaceuticals and other technology where “other researchers still have the option to invent ‘around’ the patent,” securing a patent on genetic information leaves no alternatives.²²⁵ Patents on genetic information are unique in that after a gene has been associated with a disorder, “only that gene can be used in genetic testing to compare with genetic information from potentially diseased individuals.”²²⁶ Similarly, these commentators argue that research to acquire a patent on human genetic information that leads to genetic testing does not require the same financial compensation that is commonly associated with pharmaceuticals and patents on new drugs.²²⁷ For pharmaceutical drug development, the costs associated with bringing a product to market are inflated due to “salaries for research and development scientists, the great expense of animal research and human clinical trials, and the cost of obtaining FDA approval.”²²⁸ Alternatively, due to technological developments in the area of genomic screening, critics state that there have been cases where a “disease gene has been identified one day and testing begun almost immediately.”²²⁹ Moreover, critics have pointed out that “[b]ecause the FDA does not regulate the clinical services of genetic tests . . . there is no costly FDA approval process.”²³⁰ Since the financial incentives that the patent system is supposed to foster are inappropriate and because granting patents would limit access to genetic screening that ultimately would reduce the risk of life threatening diseases, these commen-

220. Westhoff, *supra* note 14, at 9.

221. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 92.

222. *Id.*

223. *Id.*

224. See Andrews, *Gene Patents*, *supra* note 89, at 406–07.

225. Westhoff, *supra* note 14, at 8.

226. *Id.*

227. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 77.

228. *Id.*

229. *Id.*

230. *Id.*

tators adamantly argue that it is immoral for the U.S. patent law to grant protection for this type of “discovery.”²³¹

Commentators who support patenting human genetic information acknowledge that increased costs to genetic diagnostic testing could increase the likelihood for inheriting a genetic disorder.²³² These commentators argue that “there is almost no empirical data to suggest that genetic tests, or the clinical knowledge resulting from them, are negatively affected by gene patents.”²³³ Ethical considerations are typically not addressed by these commentators regardless of the multiple case studies which evidence the fact that individuals have been denied access and as a result have inherited the genetic disease.

2. *Special Status of Human Genetic Information*

Delving deeper into the ethical realm of this controversy, commentators opposing patents for human genetic information argue that the special status of human DNA and the human genome is “unique and distinctive,” and therefore “it should be treated differently from other such genomes, such as mice or maize.”²³⁴ This argument centers on the “common heritage” principle and contends that human genetic information should be a shared resource that cannot be monopolized for the benefit of one state or group of states but should be treated as to be used to the benefit of all.²³⁵ In fact, one of the original goals of the Human Genome Project was to build a publicly owned database of the entire human genome. As a result of the “race to the patent office” and the massive privatization of this information, Dr. James Watson, who began the Human Genome Project, responded by resigning from his position and stated that he had “always striven to see that the fruits of the American Dream are available to all.”²³⁶ Because it is inherently difficult to elucidate what exactly the “special nature” of human DNA is, many commentators instead argue that there exists an inalienable nature of human genetic information and that genetic information should remain publicly owned.²³⁷

Exploring the “inalienable nature” of human genetic information, commentators highlight that when dealing with an individual’s property rights,

231. See generally Andrews, *The Gene Patent Dilemma*, *supra* note 8; Westhoff, *supra* note 14.

232. Ellis, *supra* note 70, at 37.

233. *Id.*

234. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 21.

235. *Common Heritage of Mankind*, *supra* note 160.

236. Daniel Cressey, “*I Have Been Much Blessed*” – *Watson Retires*, Oct. 25, 2007, http://blogs.nature.com/news/thegreatbeyond/2007/10/i_have_been_much_blessed_watso.html (last visited Feb. 26, 2009).

237. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 22.

it is of utmost importance to respect autonomous decision-making.²³⁸ They argue that the “inalienable right to self-ownership brings with it an inalienable right to ownership of one’s body, including one’s genes,”²³⁹ therefore concluding that no one should be permitted to own, or receive temporary property rights to, another human’s genetic material.²⁴⁰

Continuing the “common heritage” argument, commentators propose that if human genetic information is going to continue to be protected by property rights, it would only be proper to have them “publicly rather than privately owned.”²⁴¹ Similar to “navigable waterways, shorelines and public parks,” commentators argue that “the public interest is protected through vesting rights of ownership in the state or some international body, or by declar[ing] that they are not amenable to ownership.”²⁴²

These arguments have been countered by commentators who state that comparing ownership of a patent on human genetic information to ownership over an individual or a specific aspect of an individual is incorrect.²⁴³ Instead, as previously mentioned, these commentators argue that gene patents are not mere discoveries but “isolated and purified” and therefore, cannot be associated with any individual human being.²⁴⁴ Further, it is argued that the critics who express concern over ownership of the person, are misled as to what patent rights confer to its owner versus ordinary property rights.²⁴⁵ Unlike typical property rights, patent rights do not grant a positive “right to use.”²⁴⁶ A patent holder is “limited to the right to exclude others from various activities involving the claimed invention, such as making, using or selling the invention in the U.S.”²⁴⁷ Thus, these commentators reject the “special nature” argument because suggesting that human genetic information has an inalienable characteristic fails to recognize that the subject of the patent is “isolated and purified” and the rights that are conferred to the owner only include the right to exclude.²⁴⁸

238. *Id.* (relating the patenting of human genetic information to the fact that “people may not be owned by others as slaves”).

239. *Id.*

240. *Id.*

241. *Id.* at 21–22.

242. *Id.* at 23.

243. Chavez, *supra* note 107, at 266.

244. *Id.* at 258.

245. Holman, *supra* note 70, at 301–02.

246. *Id.* at 302.

247. *Id.* (citing 35 U.S.C. § 271 (2006)).

248. See generally Holman, *supra* note 70.

PART IV

Proposed Alternatives: Accommodating the "Unforeseeable Nature of Inventions"

Despite the fact that the USPTO continues to grant patents for human genetic information, there still exists strong public policy and ethical concerns that must be weighed in determining whether these patents are appropriate. Those opposing human gene patents argue that simply because broad language exists throughout U.S. patent law holding that this information is patentable, it does not necessitate Congressional inaction. Although these opponents would prefer Congress to amend the Patent Act to declare human genetic information unpatentable, they accept that such an expansive approach is unlikely considering the financial influences that biotechnology has in Washington D.C. Surprisingly, even a few commentators who support human gene patents have recognized that there are occasionally cases, despite what empirical data may suggest, where gene patents negatively affect public safety and human health.²⁴⁹ While legislation to amend the Patent Act was recently rejected,²⁵⁰ Congress should still be given access to multiple proposed and available solutions. Of the many solutions that have been proposed, the two most accommodating alternatives to the current U.S. patent law framework in regard to patenting human genetic information are listed in this section.

1. Introduce "Morality" as a Subject Matter Requirement

One proposed solution is to introduce a statutory subject matter requirement that no patent may be issued if it would be contrary to public order or morality.²⁵¹ Similar provisions have been set out in international patent law such as the European Patent Convention Article 53(a), which prohibits patents on "inventions, the exploitations of which, would be contrary to 'ordre public' or 'morality.'"²⁵² The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) of the World Trade Organization (WTO) addresses this issue using similar language in Article 27.²⁵³ The European Directive on the legal protection of biotechnological inventions "prohibits patents on processes for cloning humans, the modification of the human germ line, and the use of embryos for industrial or commercial purposes."²⁵⁴

While the USPTO has yet to adopt procedures for "ethical review," scholars have recommended two "informed consent" requirements that

249. Ellis, *supra* note 70, at 21.

250. See Genomic Research and Accessibility Act, *supra* note 157.

251. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 99.

252. *Id.* (citing European Patent Convention art. 53(a), 13 I.L.M. 268, 286 (1974)).

253. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 3, at 34, 79.

254. *Id.* at 34 (citing 1998 O. J. (L 213) 13).

would contribute to determining whether the patent meets “moral” standards. Both of these standards could be used as potential springboards for generating an ethical review process. The first proposed requirement, by Nuno Pires de Carvalho, states that the “applicants for patents in the field of biotechnology disclose the source of the genetic resources eventually used as raw materials or tools in the inventive activity.”²⁵⁵ Further, Carvalho would require that the applicant include “evidence, if any, of informed consent from the research subjects.”²⁵⁶ The second proposed requirement is similar and it specifically states that “the grant of patents . . . that relate to elements of [genetic] heritage shall be subject to their having been acquired legally.”²⁵⁷

While using the above “informed consent” proposals for generating procedures to analyze whether a particular patent on genetic information meets the “morality” standards serves as a starting block, the public policy and ethical concerns enumerated in Part II of this paper must also be considered. Specifically, consideration must be given to both the potential deleterious effects on health care and the special nature of human genetic information.

2. Patent Pools

In an attempt to overcome the concern that human gene patents limit access to researchers and other third parties, many commentators recommend that Congress require the use of “patent pools” for human gene patents.²⁵⁸ While not yet mandated, this approach has been well received because the resources required “to develop any significant fraction of genetic information present in an organism” can result in a large expenditure of resources that no single company can afford.²⁵⁹ Further, if this information is not shared freely or licensed in an affordable manner, researchers

255. Marina L. Whelan, *What, if Any, Are the Ethical Obligations of the U.S. Patent Office?: A Closer Look at the Biological Sampling of Indigenous Groups*, 2006 DUKE L. & TECH. REV. 14, 23 (citing Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371 (2000)).

256. *Id.*

257. *Id.* at 25 (citing Carvalho, *supra* note 255, at 377) (enumerating that “[e]very document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin”).

258. Westhoff, *supra* note 14, at 10; Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 101; Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?*, Dec. 5, 2000, available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf> (stating that “[a] ‘patent pool’ is an agreement between two or more patent owners to license one or more of their patents to one another or third parties”).

259. Andrews, *The Gene Patent Dilemma*, *supra* note 8, at 101 (citing Clark, *supra* note 258, at 3).

would be precluded from developing new diagnostic testing.²⁶⁰ In the case of patents on human genetic information, a congressionally mandated patent pool would essentially allow for researchers “to contribute their patented genes to the pool and agree on reasonable licensing and royalty fees.”²⁶¹ For non-member researchers wanting to make use of a patent already associated with an established pool, it has been suggested that “independent organizations” could be founded to “negotiate licensing” and reduce concern over defining reasonability standards.²⁶²

Patent pools relieve concern that an individual patent holder could refuse to allow use of their patent as a means to extract exorbitant licensing fees.²⁶³ By removing transaction costs associated with acquiring multiple licenses, it is likely that gene function could be identified more easily and diagnostic tests could be more efficiently developed, and thus result in lower costs for consumers.²⁶⁴ Additionally, it removes the trepidation that genetic diagnostic testing would only be available at a few laboratories which were authorized by the original patent holder and, as a result, have overly inflated rates.²⁶⁵ Finally, pooling offers members financial security by allocating the risk of research and development to all those affiliated with the pool.²⁶⁶ While pools can be structured according to members’ preferences, it is typical that “each member of the pool receives a certain percentage of the total royalties collected by the group.”²⁶⁷ Thus, to many commentators, the increased access to make use of another researcher’s labor and the increased likelihood of recovering research and development costs makes this solution attractive.²⁶⁸

CONCLUSION

Patents on human genetic information continue to be granted by the USPTO despite multiple challenges as to whether they satisfy constitutional and patentable subject matter requirements or whether they coincide with our nation’s public policy, healthcare directives, and individual ethical concerns. It remains clear that advancements within biotechnology and the expansion of the “unforeseeable nature” of inventions will continue due to the incredible power of the human mind. Although patent protection remains the most effective way to incentivize research and disseminate that learned

260. *Id.* (suggesting a solution “similar to the pool created by the American Society of Composers, Authors and Publishers . . . [where] instead of negotiating with each holder of a copyright for thousands of songs, a radio station or bar can buy a blanket license”).

261. Westhoff, *supra* note 14, at 10.

262. *Id.*

263. *Id.* at 10–11.

264. *Id.*

265. *Id.* at 11.

266. Westhoff, *supra* note 14, at 11.

267. *Id.*

268. *Id.*

knowledge to the public, options exist for Congress to reform the United States Patent Act so that it will continue to “promote the progress of science,” allow for the recovery of research and development costs, and ensure affordable access to health care. Absent a clear directive by Congress, the U.S. Courts and the USPTO will remain bound by precedent which is unable to direct the issuance of patents that will undoubtedly contest the availability of healthcare and the ethical consideration regarding the special nature of human genetic information. As scientists continue to advance understanding of human nature, it is the role of our legislature to set standards so as to protect public health and the common good.